

REMARKS

STATUS OF THE CLAIMS

Claims 1, 2, and 8-12 are pending in this application.

35 U.S.C. §103

The Action rejects claims 1 and 8-12 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Pat. No. 5,674,844 to Kuberampath et al. (hereinafter, Kuberampath) in view of Ting et al., (1999) J. Bone and Mineral Res. 14(1):80-89 (hereinafter, Ting et al.) and further in view of Siris et al. (1998) Osteoporos Int. (hereinafter, Siris) for the reasons alleged in paragraph 9 of paper 8. Action at page 3. Applicant respectfully traverses.

As an initial matter, claims 1 and 8-12 were rejected in paragraph 9 of paper 8 as allegedly being obvious over Kuberampath in view of Ting et al., rather than being anticipated by this art. In fact, if the rejection of claims 1 and 8-12 under 35 U.S.C. § 102(b) was intended, then such rejection would clearly be improper. In particular, the Federal Circuit has stated that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Thus, art cited in combination generally cannot be the basis of a proper anticipation rejection. In any event, neither Kuberampath (alleging a treatment for increasing the bone mass or preventing bone loss) nor Siris (alleging an observational registry of postmenopausal U.S. women), alone teaches the methods of screening for an agent that modulates bone mineralization as provided in independent claim 1, and hence, cannot teach all of the limitations of dependent claims 8-12. The Action, in fact, even acknowledges that Kuberampath fails to teach the claimed invention at page 3. Therefore, neither Kuberampath nor Siris anticipate any claim of the subject application. Further, Ting et al. is not a 35 U.S.C. § 102(b) reference with respect to the application at issue, because it did not publish more than one year before the filing date of the subject application. Accordingly, if the rejections of claims 1 and 8-12 premised on 35 U.S.C. § 102(b) were intended, Applicant respectfully requests that they be withdrawn.

In the event the Action intended to reject claims 1 and 8-12 under 35 U.S.C. § 103(a) as allegedly being obvious over Kuberampath in view of Ting et al., the Applicant respectfully traverses for the reasons which follow.

As evidenced by the accompanying Declaration of the Applicant under 37 C.F.R. § 1.131, Ting et al., which published in January of 1999, is not available as prior art under 35 U.S.C. § 103(a), because the Applicant completed his invention in the United States by a date that preceded the publication of Ting et al. In particular, Dr. Ting in his Declaration states that the attached Exhibit A shows the results of an experiment that demonstrated that an increase in NELL-1 expression led to an increase in bone mineralization. As also stated by Dr. Ting, each of the dates redacted from Exhibit A is prior to January 1, 1999. Accordingly, Ting et al. is not prior art to the application at issue under 35 U.S.C. § 103(a) and hence, only Kuberampath remains to support a rejection of claims 1 and 8-12 for alleged obviousness.

Applicant notes that Dr. Ting's Declaration was previously submitted in a response mailed on March 22, 2002. The Action alleges that the Declaration is ineffective, because it recites "Exhibit A", which the Action further alleges was not attached to the Declaration. Action at page 2. Accordingly, Applicant herewith re-submits this Declaration with the aforementioned Exhibit A.

As for Kuberampath, it is clear that this art alone is insufficient to establish a *prima facie* case of obviousness. In particular, as the Examiner is aware, to establish a *prima facie* case of obviousness, a prior art reference (or references when combined) must teach or suggest all the claim limitations. In the instant case, the only independent claim at issue, namely, claim 1, relates to a method of screening for an agent that modulates bone mineralization that includes contacting a cell containing a NELL-1 gene with a test agent. Claim 1 also includes detecting an expression level of the NELL-1 gene in the contacted cell, where a difference in the expression level of NELL-1 in the contacted cell compared to an expression level of NELL-1 in a cell that is not contacted indicates that the test agent is an agent that modulates bone mineralization. For the reasons stated above, Kuberampath does not teach or suggest all of the limitations of independent claim 1. As also referenced above, the Action even acknowledges that Kuberampath does not teach a method for testing compounds which effect expression of the NELL-1 gene. See, Action at page 3. Thus, the Action fails to establish a case of *prima*

facie obviousness with respect to independent claim 1. Accordingly, as claims 8-12 depend from claim 1, these claims cannot be obvious over the cited art. Applicants respectfully request that all of these rejections be withdrawn.

The Action also rejects claim 2 under 35 U.S.C. § 103(a) as allegedly being obvious over Kuberasampath in view of Siris. Claim 2, which depends from claim 1, further provides recording agents that modulate expression of the NELL-1 nucleic acid or NELL-1 protein in a database of modulators of NELL-1 activity or in a database of modulators of modulators of bone mineralization. As related above, Kuberasampath does not teach all of the limitations of independent claim 1. Nothing in the cited text from Siris teaches or suggests a method of screening for an agent that modulates bone mineralization that includes detecting an expression level of the NELL-1 gene in a cell contacted with a test agent. Instead, as mentioned above, this art only seems to allege an observational registry of postmenopausal U.S. women. Therefore, whether viewed alone or in combination, Kuberasampath and Siris do not teach or even suggest all of the limitations of claim 1 of the subject application. As a consequence, dependent claim 2 simply cannot be obvious in view of the cited art. As the Action fails to establish a *prima facie* case of obviousness with respect to claim 2, Applicant respectfully requests that this rejection be withdrawn.

CONCLUSION

As described above, the subject application is neither anticipated nor obvious. Applicant therefore respectfully requests that all rejections be withdrawn.

In view of the foregoing, the Applicant believes all claims now pending in this Application are in a condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this Application, please telephone the undersigned at 510-769-3520.

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Respectfully submitted,



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I hereby certify that this correspondence is being deposited with the United States Postal Service first class mail in an envelope addressed to:
Assistant Commissioner for Patents, Washington D.C. 20231, on MARCH 22, 2002.

JOHNSON & JOHNSON
QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.

[Signature]
APR 24 2003
AMELIA GRITH

Attorney Docket No.: 4071-962900US
Client Ref. No.: 1999-560-1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

TING, Kang

Examiner: Ford, V.

Application No.: 09/412,297

Art Unit: 1645

Filed: October 5, 1999

For: NELL-1 ENHANCED BONE
MINERALIZATION

COPY

**DECLARATION UNDER 37 CFR § 1.131
OF KANG TING**

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, Kang Ting, declare as follows:

- 1) I am the inventor in U.S. Patent Application Serial Number 09/412,297, entitled "NELL-1 Enhanced Bone Mineralization," filed October 5, 1999 (hereinafter referred to as "the '297 application"). The '297 application is assigned to The Regents of the University of California.
- 2) Prior to January, 1999, I had completed my invention as described and claimed in the '297 application in United States of America as evidenced by the following:

a) Prior to January, 1999, I directed a research associate in my laboratory to perform von Kossa staining on test MC3T3 cells expressing NELL-1 and control MC3T3 cells expressing beta-galactosidase. This staining procedure detects calcium deposits, e.g., bone mineralization, in cells. The results of this experiment demonstrated that an increase in NELL-1 expression led to an increase in bone mineralization. This experiment is evidenced by dated slides taken of the tissue culture plates containing the von Kossa stained cells. A print out of a jpg file with a scan of those slides is attached hereto as Exhibit A.

b) Each of the dates redacted from Exhibit A is prior to January 1, 1999.

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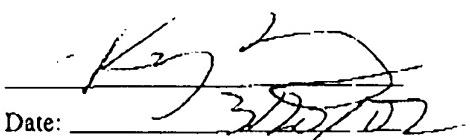
Application No.: **09/412,297**

Page 2

3) I hereby declare that all statements made herein of my own knowledge are true and that all statement made on information a belief are believed to be true; and further that these statement were made with the knowledge that willful false statement and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statement may jeopardize the validity of the application or any patent issued thereon

IN THE TESTIMONY WHEREOF I have hereunto set my signature on the date indicated below.

Kang Ting


Date: 3/22/02

COPY

COPY

Exhibit A for Declaration under 37CFR§1.131 of Kang Ting
USSN 09/412,297
Attorney Docket No. 407T-962900US

